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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/676,167	09/30/2003	Clifford A. Wright	59180.8022.US00	6780
34055	7590	05/24/2006	EXAMINER MEHTA, BHISMA	
PERKINS COIE LLP POST OFFICE BOX 1208 SEATTLE, WA 98111-1208			ART UNIT 3767	PAPER NUMBER

DATE MAILED: 05/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/676,167	WRIGHT, CLIFFORD A.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Bhisma Mehta	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 September 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 September 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Drawings*

1. The drawings are objected to because Figure 27 shows the IV compartment as reference character 15 and the catheter compartment as reference character 16. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.
2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: 165 is mentioned in lines 19 and 20 of page 8. Corrected drawing sheets in

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compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: 920, 1021, 1035, 1036. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Specification***

4. The abstract of the disclosure is objected to because it is too long and the last sentence is incomplete. Correction is required. See MPEP § 608.01(b).

5. The disclosure is objected to because of the following informalities: The specification is replete with errors. Examples of these errors are listed below but applicant should revise the specification for additional errors.

- a. In lines 11 and 28 of page 2, the use of the word "and" before the word "intravenous" appears to be incorrect.
- b. In line 5 of page 6, reference character 11 (not reference character 20) should be used for the "venipuncture site" as, in line 26 of page 7, reference character 20 has been used for the "tube receiving stop".
- c. The sentence beginning "As best" in lines 15-18 of page 7 is confusing because the mentioned reference characters are not all seen in Figure 4.
- d. In line 29 of page 9, reference character 50 (not reference character 52) should be used for the "tube access slot".
- e. In line 30 of page 10, the use of the word "do" in the sentence is incorrect.
- f. In lines 17-19 of page 11, the wording "convex tapered shaped extending" is confusing. Angle  $\alpha$  is not seen in Figure 2 as stated in lines 25-27 of page 11.
- g. Reference characters 220 and 10 in lines 13 and 16, respectively, of page 12 have been used incorrectly. The word "lenth" is incorrectly spelled in line 21 of page 12 and there is a grammatical error in the sentence beginning "The length" in line 22 of page 12.

- h. There are multiple grammatical errors in lines 6 and 7 of page 15.
  - i. In line 3 of page 16, the second occurrence of reference character 114 is incorrect.
  - j. Lines 19-22 of page 17, there appears to be a error in the use of "such as the venipuncture site 11"
  - k. In line 27 of page 19, reference character 100 is incorrectly used.
  - l. Lines 12-14 of page 20 have a grammatical error.
- Appropriate correction is required.

### ***Claim Objections***

- 6. Claims 7, 8, and 14-16 are objected to because of the following informalities: In line 2 of claim 7, the use of the word "an" appears to be an error. Also, in line 3 of claim 14, the word "connect" should be replaced with the word "connected". Appropriate correction is required.
- 7. Claim 13 is objected to because of the following informalities: In line 3 of the claim, the use of the word "that" appears to be an error. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

- 8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 17 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear how the dome can flex between about 0 degrees and about 45 degrees relative to a horizontal plane as it has not been established which portions of the dome form the angle.

### ***Double Patenting***

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 1-20 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 6827707 (Wright et al) in view of U.S. Patent No. 6,526,981 (Rozier et al). Wright et al disclose a shielding device for an I.V. connected catheter having a securement and a plastic dome with an internal wall. Wright et al also disclose pushing down on the plastic dome to hold the

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shielding device in place over a venipuncture site. Even though Wright et al disclose the invention substantially as claimed, Wright et al do not teach the specifics of the dome being flexible and having a plurality of rib members. Rozier et al disclose a shielding device where the dome is made of a plastic material which is flexible enough such that gouging a patient's skin can be avoided when pressure is applied to the dome. The dome has a plurality of grooves (38) or rib members as seen in Figure 1a. In lines 19-42 of column 8, Rozier et al also teach that the flexibility of the plastic provides cushioning such that the venipuncture site is protected and allows the shielding device to conform to one or more sites on a patient's hand. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the dome of Wright et al with grooves and make the dome of a flexible plastic material as taught by Rozier et al as both Wright et al and Rozier et al teach using a shielding device having a plastic dome for protecting a venipuncture site and Rozier et al specifically teach making the dome flexible to allow the shielding device to be used on different sites on a patient's body.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bhisma Mehta whose telephone number is 571-272-3383. The examiner can normally be reached on Monday through Friday, 7:30 am to 3:00 pm.



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
BM

KEVIN SIRMONS  
PRIMARY EXAMINER

